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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,452	06/22/2000	Fredric R. Bloom	0942.4970001/RWE/BJD	7893

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,452

Applicant(s)

BLOOM ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42,43,45-97, 103-126 and 130-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-96 and 106-126 is/are allowed.
- 6) ☒ Claim(s) 139-149 is/are rejected.
- 7) ☒ Claim(s) 42-47, 97, 103-105 and 130-138 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply, filed March 10, 2003 as Paper No. 19, to the previous Office Action. Amendments were made to the claims. Specifically, claims 44, 98-102 and 127-129 were cancelled, and new claims 130-149 were added

Claims 42, 43, 45-97, 103-126 and 130-149 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 16, mailed October 3, 2002, that is not addressed in this action has been withdrawn.

Because this Office Action contains only new rejections that are necessitated by amendment of the claims, this rejection is made FINAL.

Information Disclosure Statement

The information disclosure statement filed August 12, 2002 has been considered with the provision that reference AL1 has only been considered insofar as it relates to the Abstract of the document, there being no translation of the foreign language document outside of the Abstract; a signed and initialed copy of the form PTO-1449 is attached to this Office Action.

Claim Objections

Claims 42 and 97 (and their dependent claims) are objected to because of the following informalities: the claims do not begin with an article. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 145-149 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the rejection concerns the deposit of biological material, namely *E. coli* strains ATCC 9637, ATCC 33625, NRRL B-30143 and NRRL B-30144. It is apparent that these strains are required to practice the invention. As such, the strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the biological material. In the instant case, the process to generate the specific strains designated as ATCC 9637, ATCC 33625, NRRL B-30143 and NRRL B-3014 that is disclosed in the specification does not appear to be repeatable, nor does it appear the strains are readily available to the public. **This is a new rejection necessitated by amendment to the claims.**

The specification indicates on page 32 that strains NRRL B-30143 and NRRL B-3014 were deposited with the Agricultural Research Service Culture Collection under the Budapest Treaty on June 17, 1999. In order to fully comply with the requirements for the deposit of biological material under the Budapest Treaty, applicant must provide a statement regarding 37 CFR § 1.808 (c) wherein it is clearly indicated that upon the granting of a patent relating to the

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deposited material, all restrictions will be irrevocably removed from the strain such that it is readily available to the public.

If an applicant can adequately establish that a biological material is known and readily available, the Office will accept that showing. In those instances, however, the applicant takes the risk that the material may cease to be known and readily available. Such a defect cannot be cured by reissue after the grant of a patent. On the other hand, *Ex parte Humphreys*, 24 USPQ2d 1255 (Bd. Pat. App. & Int. 1992), held that the only manner in which applicants could satisfy their burden of assuring public access to the needed biological material, and, thereby, compliance with the enablement requirement of 35 U.S.C. 112, was by making an appropriate deposit. Those applicants that rely on evidence of accessibility other than a deposit take the risk that the patent may no longer be enforceable if the biological material necessary to satisfy the requirements of 35 U.S.C. 112 ceases to be accessible. See MPEP § 2404.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 139 and 140 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter *et al.* (*Arch. Biochem. Biophys.* **254**: 353-367, 1987, see entire document; henceforth Porter). **This is a new rejection necessitated by amendment to the claims.**

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Porter teaches the transformation of *E. coli* strain C-1a, which applicant recited as an example of *E. coli* strain C in the response to the previous Office Action mailed March 10, 2003 as Paper No. 19, with the plasmid expression vector pCQV2 (see for example the Abstract, page 355, left column, first full paragraph, and page 358, left column, first full paragraph). In order to transform this strain with the plasmid, a competent *E. coli* strain C-1a cell would necessarily be made, thereby anticipating the claimed invention.

Claims 142 and 143 are rejected under 35 U.S.C. 102(b) as being anticipated by Alterthum *et al.* (*Appl. Environ. Microbiol.* **55**: 1943-1948; see entire document; henceforth Alterthum). **This is a new rejection necessitated by amendment to the claims.**

Alterthum teaches the transformation of *E. coli* strain W (a.k.a., ATCC 9637) with the expression plasmid pLOI297 (see for example the Abstract, Table 2, and page 1945, left column first full paragraph). In order to transform this strain with the plasmid, a competent *E. coli* strain W cell would necessarily be made, thereby anticipating the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 141 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dower *et al.* (*Nucleic Acids Research* **16**: 6127-6145, 1988; see entire document; henceforth Dower) in view

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of Porter as cited in the rejection of claims 139 and 140 under 35 USC 102(b). **This is a new rejection necessitated by amendment to the claims.**

Dower teaches an efficient method of making electroporation competent cells to facilitate the transformation of *E. coli* cells for practical applications in molecular biology (see for example the Abstract)

Porter teaches the same subject matter that is disclosed in the rejection under 35 USC 102(b), as well as the fact that strain C-1a was specifically chosen for maximal expression and minimal intracellular protein degradation of the rat liver NADPH-cytochrome P-450 protein expressed by plasmid pCQV2 (see for example the Abstract).

Dower does not teach specifically using an *E. coli* strain C as a source for making electroporation competent cells.

It would have been obvious to the ordinary skilled artisan to combine the teachings of Dower with those of Porter because Dower teaches that the procedure can be used to make electroporation competent cells from an *E. coli* source, and Porter teaches that *E. coli* strain C is a valuable source of competent cells for the production of rat liver NADPH-cytochrome P-450 protein. The ordinary skilled artisan would have been motivated to combine the teachings in order to obtain a high percentage of transformants of *E. coli* strain C-1a expressing rat liver NADPH-cytochrome P-450 protein, using the electroporation competent cells taught by Dower. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when practicing the combined teachings.

Claim 144 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dower (*Nucleic Acids Research* **16**: 6127-6145, 1988; see entire document) in view of Alterthum as recited in the rejection of claims 142 and 143 under 35 USC 102(b). **This is a new rejection necessitated by amendment to the claims.**

Dower teaches an efficient method of making electroporation competent cells to facilitate the transformation of *E. coli* cells for practical applications in molecular biology (see for example the Abstract).

Dower does not teach specifically using an *E. coli* strain W as a source for making electroporation competent cells.

Alterthum teaches the same subject matter as indicated in the rejection under 35 USC 102(b), as well as the fact that *E. coli* strain W (ATCC 9637) produced the highest level of ethanol of the bacterial strains tested when expresses with plasmid pLOI1297 (see for example page 1945, left column, first full paragraph).

It would have been obvious to the ordinary skilled artisan to combine the teachings of Dower with the teachings of Alterthum because Dower teaches that the procedure can be used to make electroporation competent cells from an *E. coli* source, and Alterthum teaches that *E. coli* strain W is a valuable source of competent cells for the expression of pLOI297 in the production of ethanol. The ordinary skilled artisan would have been motivated to combine the teachings in order to obtain a high percentage of transformants of *E. coli* strain W expressing pLOI297 for the production of ethanol, using the electroporation competent cells taught by Dower. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when practicing the combined teachings.

Allowable Subject Matter

Claims 42-47, 97, 103-105 and 130-138 are objected to for containing informalities.
Claims 139-149 are rejected. Claims 48-96 and 106-126 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
May 30, 2003


DAVID GUZO
PRIMARY EXAMINER